

Substitute for form 1449A&amp;B/PTO

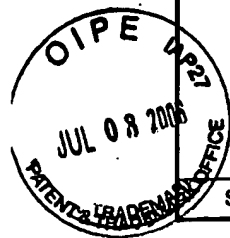
**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 4

**Complete if Known**

Application Number	10/669,099
Filing Date	September 22, 2003
First Named Inventor	Gorfine, Stephen R.
Art Unit	1655
Examiner Name	Tate, Christopher Robin
Attorney Docket Number	010692-004532US

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1.	ADAMS, M., Declaration of Dr. Michael Adams, including <i>Curriculum Vitae</i> , 22 pages, March 13, 2006.	<input type="checkbox"/>
	2.	AZARNOFF, D.L., Declaration of Daniel L. Azarnoff, M.D., including <i>Curriculum Vitae</i> , 27 pages, October 3, 2003.	<input type="checkbox"/>
	3.	BENET, L.Z. et al., "Section I: General Principles, Chapter 1: Pharmacokinetics: The Dynamics of Drug Absorption, Distribution, and Elimination" in <u>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</u> , 8th Ed., Pergamon Press, pp.1-32 (1980)	<input type="checkbox"/>
	4.	BOUGHTON-SMITH, N.K., "Nitric Oxide Synthase Activity in Ulcerative Colitis and Crohn's Disease," <i>The Lancet</i> , 342:338-340 (1999)	<input type="checkbox"/>
	5.	CELLEGY PHARMACEUTICALS INC., "Corporate Alliances," 2 pages, undated.	<input type="checkbox"/>
	6.	CHAUDHURI, G. et al., "NO is More Important than PGI <sub>2</sub> in Maintaining Low Vascular Tone in Feto-placental Vessels," <i>Am. J. Physiol.</i> 265 (Heart Circ. Physiol. 34):H2036-43 (1993)	<input type="checkbox"/>
	7.	CONANT, C.C., "Plasma Nitroglycerin Levels, Blood Pressure and Apical Heart Rate Variations to Site of Application of Nitroglycerin Ointment," <i>Nurse Practitioner</i> 13(10):56-64 (1988)	<input type="checkbox"/>
	8.	DOLLERY, C.T., Declaration of Colin T. Dollery, MB, Ch.B. FRCP., including <i>Curriculum Vitae</i> , 63 pages, May 24, 2004.	<input type="checkbox"/>
	9.	ERBA, M. et al., "Nitropaste for Prevention and Relief of Vascular Spasm," <i>AJNR</i> , 10:155-56 (1989)	<input type="checkbox"/>
	10.	FLYNN, G.L., Declaration of Gordon L. Flynn, Ph.D., including <i>Curriculum Vitae</i> , 29 pages, May 21, 2004.	<input type="checkbox"/>
	11.	FLYNN, G.L., "Topical Drug Absorption and Topical Pharmaceutical Systems," <i>Modern Pharmaceutics</i> , 2d Ed., pp. 263-64, 89 (1990)	<input type="checkbox"/>
	12.	GIBBONS, R.D., Declaration of Robert D. Gibbons, including <i>Curriculum Vitae</i> , 19 pages, May 13, 2002.	<input type="checkbox"/>

Examiner  
Signature

C. L. Tate



Date  
Considered

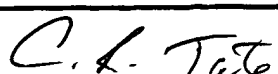
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 _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	13.	HADGRAFT, J., "Recent Developments in Topical and Transdermal Delivery," Eur. J. Drug Metab. Pharmacokinetics 21(2):165-73 (1996)	<input type="checkbox"/>
	14.	KING, D., Declaration of Denis King, 1 page, December 23, 2000	<input type="checkbox"/>
	15.	KING, D.W., "GTN in the Management of Anal Fissure," presentation slides and cover letter, 9 pages, March 7, 2001	<input type="checkbox"/>
	16.	L'HOPITAL, F. et al., "Constipation et Hypertonie du Sphincter Interne de L'Anus: Response Sphincterienne A L'Administration Sub-Linguale de 0,40 Mg de Natispray," Gastroenterol Clin Biol 14:268 (1990) with English Translation	<input checked="" type="checkbox"/>
	17.	LIPTON, S.A. et al., "A Redox-based Mechanism for the Neuroprotective and Neurodestructive Effects of Nitric Oxide and Related Nitroso-compounds," Nature 364:626-32 (1993)	<input type="checkbox"/>
	18.	LOPEZ-BELMONTE, J. et al., "The Actions of Nitric Oxide Donors in the Prevention or Induction of Injury to the Rat Gastric Mucosa," Br. J. Pharmacol. 108:73-78 (1993)	<input type="checkbox"/>
	19.	LUND, J.N., Declaration of Mr. Jonathan Lund, including Curriculum Vitae, 29 pages, March 6, 2003.	<input type="checkbox"/>
	20.	MAHAJAN, R.P. et al., "Topical Nitroglycerin Prevents the Pressor Response to Tracheal Intubation and Sternotomy in Patients Undergoing Coronary Artery Bypass Graft Surgery," Anaesthesia 48:297-300 (1993)	<input type="checkbox"/>
	21.	MATHEIS, G. et al., "Role of L-arginine-nitric Oxide Pathway in Myocardial Reoxygenation Injury," Am. J. Physiol. 262:H616-20 (1992)	<input type="checkbox"/>
	22.	MEDICAL ECONOMICS, PHYSICIANS, <u>Physicians' Desk Reference</u> , 46 Edition, pp.1004-1006; 1164-1166 (1992).	<input type="checkbox"/>
		23.	MERCK & CO., INC., "The Merck Manual of Diagnosis and Therapy, Section 3: Gastrointestinal Disorders, Chapter 35: Anorectal Disorders, General" retrieved online at < <a href="http://www.merck.com/mrkshared/mmanual/section3/chapter35/35a.jsp">http://www.merck.com/mrkshared/mmanual/section3/chapter35/35a.jsp</a> > on February 14, 2005.

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	24.	PARTEQ INNOVATIONS, "Cellegy Pharmaceuticals Acquires PARTEQ Spinoff Vaxis," 2 pages, Nov. 28, 2001	<input type="checkbox"/>	
	25.	PAVLICK, K.P. et al., "Role of Reactive Metabolites of Oxygen and Nitrogen in Inflammatory Bowel Disease," Free Radical Biology & Medicine 33(3):311-322 (2002)	<input type="checkbox"/>	
	26.	PIAZZA, C.T., Declaration of Christin T. Piazza, 2 pages, May 15, 2002	<input type="checkbox"/>	
	27.	RANADE, V.V., "Drug Delivery Systems. 6. Transdermal Drug Delivery," J. Clin. Pharmacol. 31:401-418 (1991)	<input type="checkbox"/>	
	28.	ROMANELLI, M. et al., "The Effect of Topical Nitroglycerin on Transcutaneous Oxygen," British Journal of Dermatology 124:354-357 (1991)	<input type="checkbox"/>	
	29.	SANDRINI, A. et al., "Effect of Montelukast on Exhaled Nitric Oxide and Nonvolatile Markers of Inflammation in Mild Asthma," CHEST 124:1334-1340 (2003)	<input type="checkbox"/>	
	30.	SCHOLEFIELD, J.H. et al., "A Dose Finding Study with 0.1%, 0.2%, and 0.4% Glyceryl Trinitrate Ointment in Patients with Chronic Anal Fissures," Gut 52:264-69 (2003)	<input type="checkbox"/>	
	31.	SCHOLEFIELD, J.H., Declaration of John Howard Scholefield, including Curriculum Vitae, 47 pages, Feb. 28, 2005.	<input type="checkbox"/>	
	32.	SCHOUTEN, W.R., "Pathophysiological Aspects and Clinical Outcome of Intra-Anal Application of Isosorbide Dinitrate in Patients with Chronic Anal Fissure," Gut 39(6):465-469 (1996)	<input type="checkbox"/>	
	33.	SHERMAN, M.P., "Nitric Oxide-Mediated Neuronal Injury in Multiple Sclerosis," Medical Hypotheses 39:143-146 (1992)	<input type="checkbox"/>	
	34.	SHIVELY, M., "Effect of Nitroglycerin Ointment Placement on Headache and Flushing in Healthy Subjects," Int. J. Nurs. Stud., 28(2):153-161 (1991)	<input type="checkbox"/>	
	35.	VAN REEMPTS, P. et al., "Topical Use of Nitroglycerin Ointment in Neonates," Editorial Correspondence, J. Pediatr, 116(1):155 (1990)	<input type="checkbox"/>	
Examiner Signature	C. R. Tate		Date Considered	8/7/06

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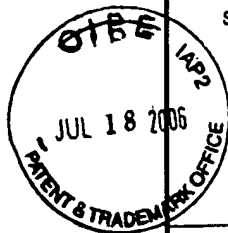
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	36.	WEINHARDT, J.A., "Making the Most of Topical Nitroglycerin," RN 48(12):38-40 (1985)	<input type="checkbox"/>

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Substitute for form 1449A/PTO

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Sheet

1

of

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**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

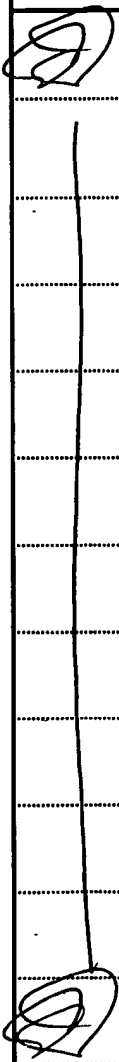
**FOREIGN PATENT DOCUMENTS**

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		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	1.	ZA	9500511	A	03-11-1996	Koren Lab Pty Ltd		<input type="checkbox"/>
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Examiner Signature	C. L. Tate	Date Considered	8/7/06
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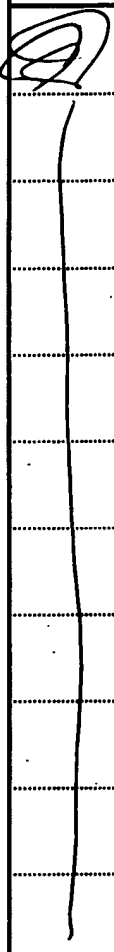

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	2.	ANONYMOUS, "ASCRS Registrants: 92nd Annual Convention - May 2-7, 1993, Hyatt Regency Chicago, Chicago, IL," List of Registrants, 34 pages [Exhibit PBL-9 to the Loder Declaration]	<input type="checkbox"/>	
	3.	ANONYMOUS, "Royal Australian College of Surgeons and Australian and New Zealand College of Anaesthetists Annual Scientific Congress- Adelaide 1993: Statistics at 14/5/93" and "A.S.C. Adelaide 1993 Scientific Programme: 10-14 May, 1993" Proceedings excerpts, 5 pages [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	4.	BROOKES, S., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Ltd -and- In the Matter of Opposition thereto by Peter Loder," 2 pages, October 11, 2000	<input type="checkbox"/>	
	5.	CRISTOFANI, K., "Anal fissures treated: Topical glyceryl trinitrate may play an important role in the management of anal fissures, US surgeons say," Australian Doctor, October 4, 1996.	<input type="checkbox"/>	
	6.	HOWES, L.G., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Ltd -and- In the Matter of Opposition thereto by Peter Loder," 2 pages, October 12, 2000, with Curriculum Vitae of Lawrence Guy Howes as Exhibit LGH-1 (26 pages).	<input type="checkbox"/>	
	7.	JONES, I.T., "The solitary rectal ulcer," presentation abstract, May 14, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	8.	KAMM, M.A. et al., "The Sir Alan Parks Physiology Unit," St. Mark's Hospital Year Book, St. Mark's Hospital, London, U.K., 2 pages [Exhibit PBL-14 to the Loder Declaration]	<input type="checkbox"/>	
	9.	KENNEDY, M.L., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Ltd -and- In the Matter of Opposition thereto by Peter Loder," 2 pages, October 12, 2000	<input type="checkbox"/>	
	10.	LODER, P.B., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Koren Laboratories Pty Limited -and- In the Matter of Opposition thereto by Peter Loder," October 11, 2000, 37 pages; with Exhibits PBL-2, 5, 8, 9, 11, 12, 14, 19, and 22-25.	<input type="checkbox"/>	
	11.	LODER, P.B., "Curriculum Vitae of Peter Bruce Loder" October 11, 2000, 14 pages [Exhibit PBL-2 to the Loder Declaration]	<input type="checkbox"/>	
	12.	LODER, P.B., "Application for Ethical Approval of Pilot Study" October 11, 2000, 15 pages [Exhibit PBL-8 to the Loder Declaration]	<input type="checkbox"/>	
		13.	LODER, P.B. et al., "Reversible chemical sphincterotomy by topical application of glyceryl trinitrate (GTN)," St. Mark's Hospital, London, U.K., presentation abstract, May 13, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>
Examiner Signature	C. R. Tate		Date Considered	8/7/06

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	14.	LODER, P.B. et al., "A new den for the winged lion: St. Mark's at Northwick Park," St. Mark's Hospital, London, U.K., presentation abstract, May 14, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	15.	LODER, P.B., Presentation Slides, May 13-14, 1993, 14 pages [Exhibit PBL-12 to the Loder Declaration]	<input type="checkbox"/>	
	16.	LODER, P.B., Letter to Dr. D.Z. Lubowski re discussion of GTN, 2 pages, July 18, 2000 [Exhibit PBL-22 to the Loder Declaration and Exhibit DZL-14 to the Lubowski Declaration]	<input type="checkbox"/>	
	17.	LODER, P.D., Email message to John Scholefield re GTN + Warts, 2 pages, August 1, 1998 [Exhibit PBL-23 to the Loder Declaration]	<input type="checkbox"/>	
	18.	LODER, P.D., Type-written notes re telephone conversations with D. Z. Lubowski, November 11, 1999 and November 28, 1999, 2 pages [Exhibit PBL-25 to the Loder Declaration]	<input type="checkbox"/>	
	19.	LUBOWSKI, D.Z., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Limited -and- In the Matter of Opposition thereto by Peter Bruce Loder," October 16, 2000, 14 pages; with Exhibits DZL-1, 9, and 14]	<input type="checkbox"/>	
	20.	LUBOWSKI, D.Z., "Curriculum Vitae of David Z. Lubowski," 38 pages, October 16, 2000 [Exhibit DZL-1 to the Lubowski Declaration]	<input type="checkbox"/>	
	21.	LUBOWSKI, D.Z. et al., "A radio-isotope study of colonic function during defaecation," St. George Hospital, Sydney, presentation abstract, May 13, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	22.	LUBOWSKI, D.Z., "Anorectal physiology - Is it useful in rectal prolapse?," St. George Hospital, Sydney, presentation abstract, May 14, 1993 [Exhibit PBL-11 to the Loder Declaration]	<input type="checkbox"/>	
	23.	LUBOWSKI, D.Z., Letter to Dr. P. B. Loder re discussion of GTN with reply by Peter B. Loder, 3 pages, July 25, 1998 [Exhibit DZL-14 to the Lubowski Declaration and Exhibit PBL-22 to the Loder Declaration]	<input type="checkbox"/>	
	24.	MARCHEI, C., "Statutory Declaration: In the Matter of Australian Patent Application No. 708694 in the Name of Cellegy Australia Pty Ltd -and- In the Matter of Opposition thereto by Peter Loder," 2 pages, October 11, 2000	<input type="checkbox"/>	
	25.	PHILLIPS, R.K.S., Letters dated October 29, 1998 and May 12, 1998 regarding invitation to lecture at St. Mark's Hospital, 7 pages [Exhibit DZL-9 to the Lubowski Declaration]	<input type="checkbox"/>	
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	26.	SCHOLEFIELD, J., Email messages to Peter Loder, including 1 from Peter Stein, regarding Gorfine patent application, 4 pages, April 1, 1997 [Exhibit PBL-19 to the Loder Declaration]	<input type="checkbox"/>
	27.	SCHOUTEN, W.R., "Lateral internal sphincterotomy in the treatment of Hemorrhoids: A clinical and manometric study" Dis Colon Rectum 29:869-72 (1986) [Exhibit PBL-5 to the Loder Declaration]	<input type="checkbox"/>
	28.	STEIN, P.M., Letter to Dr. Peter B. Loder regarding circumstances surrounding meeting, 3 pages, September 18, 2000 [Exhibit PBL-24 to the Loder Declaration]	<input type="checkbox"/>
			<input type="checkbox"/>

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